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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,293	04/04/2001	Mike Farwick	P 280108 000561 BT	4063

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/09/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/825,293

Applicant(s)
Farwick et al.

Examiner
Christian L. Fronda

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 26, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17, 22, and 23 is/are allowed.
- 6) ☒ Claim(s) 18-21 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 10, 2001 is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9, 14 6) ☐ Other:

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DETAILED ACTION

1. In the **SUPPLEMENTAL AMENDMENT UNDER 37 C.F.R. 1.111** dated June 26, 2002 (Paper No. 14), Applicants have amended claims 17-23.
2. Claims 17-27 are under consideration in this Office Action.

Information Disclosure Statement

3. The information disclosure statement filed November 9, 2001, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.
4. The information disclosure statement filed 6/26/2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Priority

5. Acknowledgment is made of applicants' claim for foreign priority under 35 U.S.C. 119 (a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Drawings

6. The drawings filed on 05/10/2001 are accepted by the Examiner.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18-21 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a protein comprising SEQ ID NO: 2 wherein the protein has acyl carrier protein activity, an isolated polynucleotide of the nucleotide sequence of nucleotides 58-348 of SEQ ID NO: 1 wherein the polynucleotide encodes a polypeptide having acyl carrier protein activity, and an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1 wherein the polynucleotide encodes a polypeptide having acyl carrier protein activity; does not reasonably provide enablement for any isolated polynucleotide encoding a protein with an amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to that of SEQ ID NO: 2 wherein said protein has acyl carrier protein activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed April 11, 2002 (Paper No. 12) have been fully considered but they are not persuasive. Applicants' position is that the Examiner's position for the enablement requirement to be met is inappropriate, the invention is enabled by the guidance provided in the specification, and the experimentation required is not undue and is well within the skill of an ordinary molecular biologist to synthesize or recombinantly construct the claimed sequences. The Examiner disagrees with Applicants' position for the reasons stated below.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any isolated polynucleotide encoding a protein with an amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to that of SEQ ID NO: 2 wherein said protein has acyl carrier protein activity. The specification provides guidance and examples for making an isolated polynucleotide a protein comprising SEQ ID NO: 2 wherein the protein has acyl carrier protein activity, an isolated polynucleotide of the nucleotide sequence of nucleotides 58-348 of SEQ ID NO: 1 wherein the polynucleotide encodes a

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polypeptide having acyl carrier protein activity, and an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1 wherein the polynucleotide encodes a polypeptide having acyl carrier protein activity. However, the specification does not teach the specific catalytic/binding amino acids and the structural motifs which are essential for protein/enzyme structure and activity/function. The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed polynucleotides is enormous and entails selecting specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in a polynucleotide encoding SEQ ID NO: 2 to make the claimed polynucleotide encoding a protein with an amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to that of SEQ ID NO: 2 and determining by enzyme or binding assays whether the polynucleotide encodes a protein that has acyl carrier protein activity. The specification does not provide guidance with respect to the specific binding/catalytic amino acids and the structural motifs essential for protein/enzyme structure and activity/function which must be preserved. Thus, searching for the specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in a polynucleotide encoding SEQ ID NO: 2 to make the claimed polynucleotide encoding a protein with an amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to that of SEQ ID NO: 2 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polynucleotide encodes a protein that has acyl carrier protein activity is extremely low since no information is provided by the specification regarding the specific binding/catalytic amino acids and the structural motifs essential for protein/enzyme structure and activity/function which must be preserved.

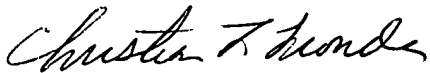
The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for protein/enzyme structure and activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 24-27 which depend from any one of defective claims 18-21 are also rejected because they do not correct the defect of any one claims 24-27.

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Conclusion

9. Claims 17, 22, and 23 are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.



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Technology Center 1600
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